

REMARKS

Claims 1, 3, 7-12, 15-26, and 33 are pending and under consideration for purposes of the instant Office Action. Claims 2, 4-6, and 13-14 were previously canceled, and claims 27-33 were previously withdrawn.

Claim 1 has been amended to more particularly recite the tablet configuration according to the subject invention. Applicants respectfully submit that the amendments are supported by the specification and that no new matter is entered by said amendments. Specifically, support is provided in the specification, including the accompanying drawings, which describe or show the inactive and active layers of the tablets as recited in the claims, where the active segments are formed by the divided active layer. Reconsideration of claims 1, 3, 7-12, 15-26, and 33, as amended, is respectfully requested in view of the further amendments to the claims submitted in this Reply.

Applicants thank the Examiner for the careful consideration of the previous amendments and accompanying remarks, finding them persuasive to overcome the prior rejections under 35 USC 103(a). However, new grounds for rejection have been presented against the claims. These newly presented rejections are discussed below:

New Rejections under 35 USC 103(a)

Claims 1, 3, 7-12, 15-26, and 33 stand rejected as being unpatentable under 35 USC 103(a), citing Langauer (US Pat. No. 3,723,614), in view of Ting, et al. (WO 00/18447). Applicants respectfully traverse.

The Office Action identifies Langauer as describing a scored tablet for accurate breaking and administration of the active from the separate tablet portions. However, the Office Action further admits that Langauer fails to describe a tablet having a segment containing either an undetectable amount of drug or a pharmacologically ineffective amount of drug (i.e., an *inactive* segment).

The Office Action then cites the reference of Ting, and asserts that it would have been obvious to make a scored tablet of Langauer and combine it with a tablet having two immediate release compartments substantially enveloped by a scored extended release compartment, as described by Ting, to produce the instant invention. Applicants disagree, since combining Langauer and Ting would only provide scored tablets of Langauer (as the active portions) enveloped by a scored extended release composition (the inactive portion). However, the subject invention is different than this “combination” resulting from Langauer and Ting.

Applicants note that the claims, as currently amended, further clarify the distinctions between the subject invention and a Langauer/Ting combination. Specifically, the currently claimed invention recites that the active layer is divided to form substantially identical first and second unitary segments that have only one face which contacts the inactive segment. The active portions of a Langauer/Ting combination tablet are not formed from a “divided” layer; rather, the active portions of a Langauer/Ting tablet are discrete tablets formed individually prior to being “coated” or “substantially enveloped” by (i.e., posited within) the inactive composition.

Advantageously, the subject tablets can be formed using a conventional bi-layer tablet press and can provide the unexpected result of forming three or more segments from only two layers (one layer forming the inactive segment and one divided layer forming two active segments.) This is not achieved by Langauer or Ting individually or combined, since forming the two active portions each require a compression step, and the inactive “envelope” requires a third compression step.

Moreover, the active unitary segments of the claimed invention have only one face which is in contact with the inactive layer or segment. In contradistinction, the active portions of a Langauer/Ting combination necessarily have more than one face in contact with the inactive portion since they are “substantially enveloped” by the inactive composition. Ting describes envelopment of the active portions by “press coating” the active portions with the inactive composition. By having only one face of the active segments in contact with the inactive layer, the subject tablets do not have any active portion “substantially enveloped” by the inactive composition.

Not only would a Langauer/Ting combination tablet require three compression steps, as discussed above, but the press-coating envelopment step can further require specialized press-coating machinery or tooling. Such required machinery or tooling can be avoided by the conventional layered tablet press process employed in the manufacture of the subject invention.

Neither Langauer nor Ting et al. references teach or suggest a readily divisible tablet which has an inactive layer/segment which contacts only one face of each active layer/segment. Further, there is no motivation provided in the prior art to modify the dosage forms described in Langauer or Ting et al. which would lead a person of ordinary skill in the art to the unique and unobvious tablets of the claimed invention. Accordingly, applicants believe the claimed invention is unobvious in view of Langauer or Ting taken separately or combined. In view of the above amendments to the claims, and the accompanying remarks, withdrawal of the rejection under 35 USC 103(a), citing Langauer in view of Ting et al., is therefore respectfully requested upon reconsideration.

Claims 17-18 are rejected as being unpatentable under 35 USC 103(a), citing Langauer (US Pat. No. 3,723,614) in view of Ting, et al. (WO 00/18447), and further in view of Addicks, et al. (US 5,041,430). The rejection reiterates the rationale behind the citation of Langauer and Ting, and uses Addicks for its disclosure of employing warfarin in the tablet. Applicants' position, as discussed above, regarding the failure of Langauer or Ting, separately and together, to make obvious the claimed invention is incorporated herein by reference.

Therefore, irrespective of the use of warfarin, the Addicks reference does not cure the defects of Langauer or Ting, taken separately or combined. Addicks does not teach or describe a tablet configured as claimed – namely, a tablet comprising a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment – i.e., the active is not enveloped by the inactive.

In view of these defects of Langauer and Ting, even if combined with Addicks, applicant submits that the claimed invention would not have been obvious in view of these references. Combining Addicks with the Langauer and/or Ting references would only provide a teaching of two warfarin-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Addicks reference with Langauer and/or Ting, et al., is not the claimed invention. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 17 and 19 are rejected as being unpatentable under 35 USC 103(a), citing Langauer (US Pat. No. 3,723,614) in view of Ting, et al. (WO 00/18447), and further in view of Eberlin, et al. (US 3,696,091). The rejection again reiterates the rationale behind the citation of Langauer and Ting, and uses Eberlin for its disclosure of employing digoxin in the tablet.

Applicants' position, as discussed above, regarding the failure of Langauer or Ting, separately and together, to make obvious the claimed invention is incorporated herein by reference. Moreover, irrespective of the use of digoxin, the Eberlin reference does not cure the defects of Langauer or Ting. Eberlin does not teach or describe a tablet having a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment – i.e., the active is not “substantially enveloped” by the inactive.

In view of these defects of Langauer and Ting, even if combined with Eberlin, applicant submits that the claimed invention would not have been obvious in view of these references. Combining Eberlin with the Langauer and/or Ting references would only provide a teaching of two digoxin-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Eberlin reference with Langauer and/or Ting, et al., is not the claimed invention. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 17 and 20 are rejected as being unpatentable under 35 USC 103(a), citing Langauer (US Pat. No. 3,723,614) in view of Ting, et al. (WO 00/18447), and further in view of Franz, et al. (US 6,555,581). The rejection again reiterates the rationale behind the citation of Langauer and Ting, and uses Franz for its disclosure of employing levothyroxin in the tablet.

Applicants' position, as discussed above, regarding the failure of Langauer or Ting, separately and together, to make obvious the claimed invention is incorporated herein by reference. Moreover, irrespective of the use of levothyroxin, the Franz reference does not cure the defects of Langauer or Ting. Franz does not teach or describe a tablet having a first inactive segment, one face of which is contiguous with an active layer divided to form first and second unitary active segments where only one of the faces of the active segments contacts the inactive segment – i.e., the active is not “substantially enveloped” by the inactive.

In view of these defects of Langauer and Ting, even if combined with Franz, applicant submits that the claimed invention would not have been obvious in view of these references. Combining Franz with the Langauer and/or Ting references would only provide a teaching of two levothyroxin-containing tablets substantially enveloped by an inactive composition. This tablet configuration arrived at by combining the Franz reference with Langauer and/or Ting, et al., is not the claimed invention. Reconsideration and withdrawal of this rejection is respectfully urged.

Applicants note the Examiner's acknowledgement of the submission of terminal disclaimers in the subject application. The obviousness-type double patenting rejections were maintained until such time that the terminal disclaimers were accepted. Applicants further note that the terminal disclaimers are accepted and respectfully request that the obviousness-type double patenting rejections be withdrawn.

Applicants believe the subject claims, as amended, are now in condition for allowance, and respectfully request that a Notice of Allowance be issued for the instant application.

Should further information or clarification be required on any of these matters, applicants invite the Examiner to contact the undersigned at the address or phone/fax number provided below.

Respectfully submitted,

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